

**FMC Corporation**

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IV-D-006



October 2, 2001

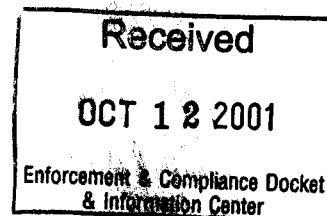
Joseph Retzer  
Director, Collection Strategies Division  
US Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Dear Mr. Retzer:

FMC Corporation (FMC) is pleased to comment on the Information Collection Request document listed as ICR No. 2002.02 issued for the proposed EPA Cross-Media Electronic Reporting and Recordkeeping Rule (CROMERRR). EPA submitted the document to the Office of Management and Budget (OMB) for approval with an OMB decision on the ICR due between 30 and 60 days after August 31, 2001.

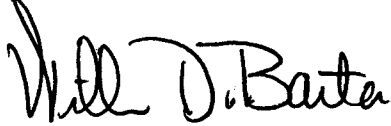
FMC is a diverse chemical company engaged in the development, manufacture and sales of agricultural products, industrial chemical, specialty chemicals, food ingredients and pharmaceutical excipients. We appreciate the EPA efforts to formulate electronic submission and recordkeeping and thank you for the opportunity to comment on the financial impact of CROMERRR. The comments will focus on the impact to those organizations regulated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (40 CFR Part 160) and the Toxic Substances Control Act (TSCA) (40 CFR Part 792) Good Laboratory Practice Standards (GLPs).

Please find attached a Summary and discussion points document based on the 40 CFR Parts 3, 51, etc. Establishment of Electronic Reporting: Electronic Records; Proposed Rule, Federal Register volume 66, Number 170, August 31, 2001; 46162 - 46195 and ICR 2002.02.



Sincerely,

William D. Barta

A handwritten signature in black ink that reads "Will D. Barta". The signature is written in a cursive, flowing style.

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FMC Corporation  
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cc: Desk Officer For EPA, Office of Information and Regulatory  
Affairs, Office of Management and Budget

## **SUMMARY**

Electronic reporting and record keeping is an important initiative with potential to improve efficiency in information management and the productivity of industry and government. FMC appreciates EPA's efforts in this regard. However, as a participant in the crop protection industry we would like to point out the importance of ensuring that EPA's proposals address the special requirements embodied under US pesticide law, FIFRA, as well as TSCA. We believe EPA has not adequately factored FIFRA/TSCA issues into the CROMERRR cost benefit analyses and risk assessments for OMB and we recommend EPA reassess CROMERRR compliance costs on the FIFRA/TSCA regulated industry before finalizing the rule.

The EPA Office of Environmental Information (OEI) promulgated the proposed Cross-Media Electronic Reporting and Recordkeeping Rule (CROMERRR) on August 31, 2001 to offer the option of submitting environmental reports electronically and maintaining electronic records. The rule is designed for modest sized reports and supporting data. However, the proposed rule also impacts the FIFRA/TSCA Good Laboratory Practice (GLP) community. FIFRA submissions are at least 60,000 pages and are supported by prodigious amounts of data (greater than 500,000 pages/submission).

CROMERRR significantly impacts the GLP community on three issues:

### **Voluntary Option**

By stating that the rule is strictly voluntary but containing language that is clearly contrary to the fact, challenges the entire FIFRA/TSCA community to bear the increased costs of compliance with no possible alternatives. GLP facilities currently must keep electronic records to be competitive. In addition companies choosing electronic submission will have a competitive advantage.

### **Cost of Electronic System Compliance**

OEI seems to assume one system/reporting facility. GLP facilities have multiple systems; a medium size facility could easily have 30 systems of varying complexity and cost. All of these systems would require upgrading, replacement or enhancements to comply with CROMERRR. This is a significant undertaking in terms of manpower and expense.

### **Record Retention Requirements**

FIFRA GLPs require record retention for the duration of a registration which may exceed 30 years. This would require migration of electronic records due to system obsolescence every 5-7 years. Migration is an intensive, expensive process if record integrity is to meet CROMERRR standards.

## **DISCUSSION POINTS**

### **CROMERRR Milestone Dates**

EPA recently published the proposed Cross-Media Electronic Reporting and Record-keeping Rule ("CROMERRR"), 66 Fed. Reg. 46162 (Aug. 31, 2001) to offer an electronic reporting option for environmental reports by EPA regulated entities and to maintain EPA records electronically. Comments are due to EPA by November 29, 2001, and EPA suggests sending comments to OMB by October 1, 2001.

### **CROMERRR Approach to Electronic Submission and Recordkeeping**

The proposed rule emphasizes electronic submission and recordkeeping for environmental reports. These reports are modest in size with limited supporting data. However, the rule also impacts the industrial chemical and agricultural chemical industry submitting reports and registrations supported by EPA FIFRA/TSCA Good Laboratory Practice Standards (GLPs). GLPs require rigorous data collection practices, reporting and lengthy data retention procedures. The public meeting in Washington (July, 2000) revealed, that the EPA Office of Environmental Information, promulgators of CROMERRR, were completely unaware of the FIFRA registration size (a minimum 60,000 pages) with a supporting document collection exceeding 500,000 pages. OEI admitted that they had no capability to receive a submission of that volume. Thus, even though the FIFRA submissions are small in number they far exceed in size the typical environmental reporting submission.

Examination of the proposed CROMERRR and ICR 2002.02 documents suggest the EPA did not consider the unique regulatory requirements for the FIFRA/TSCA community and, therefore, were not part of analyses and risk assessments. We believe the numbers stated in the average annual cost and average annual savings do not reflect the true annual costs and savings (if any) to the FIFRA/TSCA regulated companies.

### **FIFRA/TSCA Issues**

**ISSUE:** The proposed rule offers electronic report submission and recordkeeping as "voluntary".

**CROMERRR:** An electronic record is defined as "...any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system."

**Discussion:** The key point is that an electronic record does not need to be data collected online but any manipulation, tabulation, analyses, distribution, storage, etc. qualifies it as an electronic record. In the FIFRA/TSCA world this means electronic documents have existed for at least 20 years for anyone employing computers to collect, analyze and tabulate data. Any company submitting FIFRA registrations or TSCA Test Rule data and reports automatically fall under the electronic recordkeeping rule simply by keeping current with modern scientific instrument and computer technology. In today's electronic age, regulated corporations must collect and store data on a computer to remain competitive and/or create a competitive advantage.

Another concern is that EPA reviewers may give preferential treatment to electronic submissions. The reviewer ease of locating, evaluating, distributing and reporting their assessments with the electronic system may create a bias against paper submissions and therefore, could penalize registrants that submit on paper. This bias would force submitters to use electronic systems to assure submissions are reviewed in a timely manner.

The EPA Laboratory Data Integrity Branch has estimated that there are more than 1000 laboratory and field sites within the FIFRA GLP

program and most of these facilities would be impacted by CROMERRR. This number far exceeds the "Average Annual Facilities" which are expected to acquire or set up electronic recordkeeping systems as stated in the ICR (2002.02).

In conclusion CROMERRR is involuntary for the FIFRA/TSCA regulated community for electronic records and may prove to be de facto required for electronic submissions for competitive reasons.

#### **ISSUE: Cost of Electronic Systems**

##### **CROMERRR: Nominal Cost of Compliance**

**Discussion:** The EPA analysis is skewed toward the modest size of environmental reports and supporting data. The FIFRA/TSCA community maintains multiple systems whereas the EPA assumption is "one system per site". A midsize enterprise like FMC possesses at least 30 electronic systems of varying size and complexity in its FIFRA GLP operations.

Companies currently have multiple "legacy" computer systems and software packages that would be non-compliant with CROMERRR and would have to be upgraded or replaced. That implies that a large, up-front capital cost would have to be implemented to bring all required systems up to an acceptable level under CROMERRR. If vendor technology does not exist for a compliance requirement, the company may choose to write software and thereby incur programming, specifications, coding, and validation activities at significant effort and expense. New software and upgrades still incur validation and support costs. In the CROMERRR proposal EPA estimated "The average annual cost to implement a new electronic record keeping system is \$40,000 for each facility...". Given the number of systems within a GLP facility, these costs can be substantial.

CROMERRR may also apply to other types of GLP records such as the master study schedule, standard operating procedures (SOPs), training records, curriculum vitae and facility records.

#### **ISSUE: Data Migration**

##### **CROMERRR: Maintain Electronic Record for the Required Time**

**Discussion:** FIFRA GLPs require retention of reports and raw data for the lifetime of the product registration which can easily exceed 30 years. The rapid evolution of software and hardware guarantees obsolescence of computer systems and creates the dilemma of maintaining legacy systems or migrating to new media every 5-7 years. Maintaining old software is problematic and eventually all systems would need to be migrated. Migration involves extensive planning, error checking and periodic review of electronic record integrity to detect system degradation. Accurate data migration is a time-consuming and expensive exercise especially maintaining the metadata, audit trails and electronic signatures. Migrating a department database from extinct software to Oracle, for example, cost \$60,000 and does not include the CROMERRR requirements.

In conclusion we believe CROMERRR imposes a significant financial burden on the FIFRA/TSCA community which was not factored into the CROMERRR cost benefit analyses. We urge EPA to re-evaluate the CROMERRR compliance costs before rule finalization.